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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,087

09/09/2003

Harri Heino

12808/25

9855

23838 7590 04/13/2009

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EXAMINER

SIGLER, JAY R

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

04/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,087	Applicant(s) HEINO ET AL.	
	Examiner JAY R. SIGLER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, Species A in the reply filed on 29 January 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. It is noted that claims drawn to the non-elected invention have been canceled.

Drawings

3. The drawings were received on 11 September 2008. These drawings are unacceptable for the following reason: Fig. 4C contains new matter.
4. The amendment filed 11 September 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in Fig. 4C, the band is shown with added lines (one of which the number 62 appears to be designated) which make the band appear to be two separate bands. The original Fig. 4C does not show these lines.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 contains the language “[a] method to secure a bone fracture **or** osteotomy” (l. 1; emphasis added) and “tightening the band to secure both sides of the bone fracture together” (l. 10) render the claim indefinite. The preamble allows for the method to be used with a bone fracture or osteotomy while the language of line 10 limits the claim to a bone fracture. It is unclear whether the claimed method can be used with a either a bone fracture or osteotomy; or with just a bone fracture. The claim will be considered to be able to be used with either a bone fracture or osteotomy for further examination.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,466,262 to Saffran (hereinafter "Saffran").

Saffran discloses providing a bioabsorbable band system (see col. 7, l. 29-32; can biodegrade in situ), comprising: a bioabsorbable band (12;) having a first end and a second end; a first locking system comprising at least one bioabsorbable fastener (15); and a second locking system comprising at least one bioabsorbable fastener (15); locking the first end of the band to a surface of a bone with the first locking system (15 can be a staple); wrapping the second end of the band around side edges of the bone (see Fig. 2a); tightening the band to secure both sides of the bone together (see col. 4, l. 43-44); and locking the second end of the band to a surface of the bone (embodied by attaching another staple 15).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,112,221 to Harris (hereinafter "Harris") in view of US 2002/0120270 to Trieu et al. (hereinafter "Trieu").

a. Concerning claim 14: Harris discloses providing a band system (see Fig. 10), comprising: a band (51) having a first end and a second end; a locking

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system comprising at least one fastener (65); wrapping the second end of the band around side edges of the bone (see Fig. 10); tightening the band to secure both sides of the bone together (see col. 2, l. 20-23); and locking the second end of the band to a surface of the bone (using 63 and 65).

Harris does not disclose a second fastener that is inserted through the first end of the band; or using bioabsorbable materials. Trieu however discloses the step of inserting a fastener (32a) through the first end of a band (30) and into bone (V1) while a band is tensioned (see ¶ 76) in order to keep the band in place. It would have been obvious to someone of ordinary skill in the art at the time of the invention to add the step of inserting a fastener through the first end of the band in the method of Harris in order to hold the band in place while tensioning as suggested by Trieu.

Trieu further discloses using bioabsorbable materials (see ¶ 34) if a permanent implant is not needed. It would have been obvious to someone of ordinary skill in the art at the time of the invention to use bioabsorbable materials in the invention of Harris, in view of Trieu, if a permanent implant is not needed. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

b. Concerning claim 15-18: Harris further discloses drilling through the first and second end to attach the second end (see Fig. 10) which allows the surgeon to pick the hole position. It would have been obvious to drill through the first end

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to attach the fastener in the modified invention of Harris, in view of Trieu, in order to allow the surgeon to be able to pick the hole position.

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Harris in view of Trieu as shown above and further in view of US 5,423,821 to Pasque (hereinafter "Pasque").

Harris discloses a needle attached to the second end (see col. 8; 1st paragraph) Harris, in view of Trieu, does not specifically suggest inserting the needle through tissue to be drawn together with the bone. Pasque however suggests drawing tissue to bone using a band when closing a sternum to minimize bleeding of surrounding tissue (see claim 1). It would have been obvious to someone of ordinary skill in the art at the time of the invention to add the step of drawing tissue to bone using the needle in the modified invention of Harris, in view of Trieu, when closing a sternum to minimize bleeding of surrounding tissue as suggested by Pasque.

Response to Arguments

12. Applicant's arguments with respect to claims 14-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
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